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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,754	10/20/2000	Neil Berinstein	13115	7885

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
05/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/693,754	BERINSTEIN ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-27 and 29-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-27 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e) and a submission as required under 37 CFR 1.114, was filed on 10/31/07 in this application after final rejection and subsequent abandonment, along with a Petition to Revive an Unintentionally Abandoned Application under 37 CFR 1.137(b). Applicant's petition was granted on 3/28/08. Since this application is now eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered. Claims 3 and 28 are canceled and new claims 29-31 have been added. Claims 1-2, 4-27, and 29-31 are pending in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in the instant action can be found in the previous office action.

Information Disclosure Statement

The information disclosure statement filed 8/13/07 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 for the following reasons. The IDS of 8/13/07 was submitted after final along with a Request for Continued Examination (RCE). The RCE was deemed improper as it was not accompanied by a submission as required by 37 CFR 1.114, see

the action mailed on 8/21/07. As such, the IDS of 8/13/07 was treated as an IDS submission after final. The information disclosure statement filed 8/13/07 therefore fails to comply with 37 CFR 1.97(d) because it lacks a statement as specified in 37 CFR 1.97(e). It is further noted that the applicant did not resubmit the IDS with the second RCE filed on 10/31/07.

The IDS of 8/13/07 has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Duplicate Claims

Applicant is advised that should claim 20 be found allowable, claim 29 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC 103

The rejection of claims 1-2, 4-17, and 20 under 35 U.S.C. 103(a) as being unpatentable over Hurpin et al. (1998) Vaccine, Vol. 16 (2/3) 208-215, in view of Hodge et al. (1997) Vaccine, Vol. 15, No. 6/7, 759-768, US Patent No. 6,127,116 (10/3/00), filed on 3/4/97 and hereafter referred to as Rice et al., and Lehner et al. (1999) J. Infect. Dis., Vol. 179 (Suppl 3), S489-S492, is maintained over previously pending and new claims 1-2, 4-17, 20, and 29-30. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that Hurpin et al. in view of Hodge et al., Rice et al., and Lehner et al. does not provide the requisite reasonable expectation of success that intranodal immunization would induce or enhance an immune response. In particular, the applicant argues that Lehner et al. cannot be relied upon for providing the reasonable expectation of success because the technique used by Lehner, targeted iliac lymph node administration, is not direct intranodal administration of antigen. The applicant further argues that the specification provides a comparison of a subcutaneous route of administration, which applicant contends is similar to that of Lehner, and intranodal administration and shows that while the subcutaneous route did not generate an immune response greater than the saline control, the intranodal route resulted in a substantial immune response. Thus, the applicant concludes that no reasonable expectation of success in inducing or enhancing an immune response can be found in the combined teachings of Hurpin et al., Hodge et al., Rice et al., and Lehner et al.

In response, it is first noted that Hurpin et al. teaches the successful generation of anti-53 CTL responses in mice following either a single or multiple intrasplenic injections of ALVAC encoding p53. As previously noted, the spleen is a lymphatic tissue. Thus, Hurpin shows that

administration to lymphatic tissue can induce antigen specific immunes which can be increased by subsequent administrations also to lymphatic tissue. Further, as discussed in detail in the previous office action, Rice et al. teaches that administration of antigen directly or indirectly to lymph nodes is a preferred method of immunization. Lehner et al. was cited for demonstrating that the delivery of an antigen such that the lymph node is targeted generates increased immune responses to the antigen as compared to other routes of administration. As stated in previous office actions, Lehner et al. showed that a direct comparison of intramuscular versus intradermal versus targeted iliac lymph node immunization revealed that targeted iliac lymph node administration of antigen resulted in increased T and B cell mediated antigen-specific immune responses (Lehner et al., page S489, and page S491). The targeted iliac lymph node administration technique, while subcutaneous, administers the antigen close to both the internal and external iliac lymph nodes, ensuring direct exposure of the lymph nodes to the administered antigen. Applicant's subcutaneous administration technique, on the other hand, was not designed to target any particular lymph nodes, and while the applicant states that the dorsal cervical/ interscapular region is known to contain lymph nodes in the mouse, there is no indication in the specification that the applicant's subcutaneous injections were in fact administered in close proximity to any particular lymph node or nodes in the dorsal cervical/ interscapular regions. Thus, applicant's subcutaneous administration technique does not appear to be analogous to the targeted lymph node administration technique used successfully by Lehner et al. Further, the rejection of record is based on the knowledge available to the skilled artisan at the time of filing. Lehner et al., as discussed above and in previous office actions, clearly demonstrates successful generation of immune response by targeted administration of antigen in close proximity to lymph

nodes. In addition, all of Hurpin et al., Rice et al., and Lehner et al., teach that lymphatic administration successfully generates immune responses, and Rice and Lehner et al. particularly point to targeting the lymph node either directly or indirectly with antigen to induce immune responses. Taken as a whole, the combined teachings of the cited references demonstrate that the skilled artisan at the time of filing would have had a reasonable expectation that direct intranodal administration of an antigen would induce an immune response. The applicant is also reminded that obviousness does not require absolute predictability of success; for obviousness under 35 U.S.C. § 103, all that is required is a reasonable expectation of success. See *In re O'Farrell*, 7 USPQ2d 1673 (CAFC 1988).

Thus, for reasons of record, the rejection stands.

The rejection of claims 18-19 under 35 U.S.C. 103(a) as being unpatentable over Hurpin et al. (1998) Vaccine, Vol. 16 (2/3) 208-215, in view of Hodge et al. (1997) Vaccine, Vol. 15, No. 6/7, 759-768, US Patent No. 6,127,116 (10/3/00), filed on 3/4/97 and hereafter referred to as Rice et al., and Lehner et al. (1999) J. Infect. Dis., Vol. 179 (Suppl 3), S489-S492, as applied to claims 1-2, 4-17, 20, and 29-30 above, and further in view of Zaremba et al. (1997) Canc. Res., Vol. 57, 4570-4577 and Salgaller et al. (1996) Canc. Res., Vol. 56, 4749-4757, is maintained. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

Applicant's arguments are based on their previous argument that Hurpin in view of Hodge, Rice, and Lehner do not provide a reasonable expectation of success to arrive at the instant invention as claimed. These arguments have been fully considered and addressed in detail

above and have not been found persuasive. Applicant's further argument that Zaremba et al. and Salgaller et al. do not overcome the deficiencies of Hurpin, Hodge, Rice, and Lehner is not persuasive as the teachings of Hurpin, Hodge, Rice, and Lehner stand, as discussed above, and Zaremba and Salgaller were not cited to teach lymph node administration, rather these references were cited to provide teachings and motivation to immunize with tumor antigens which comprise the sequence YLSGADLNL or YLEPGPVTV. The applicant has not traversed these teachings, therefore, the rejection of record stands.

The rejection of claims 21-27 under 35 U.S.C. 103(a) as being unpatentable over Hurpin et al. (1998) Vaccine, Vol. 16 (2/3) 208-215, in view of Hodge et al. (1997) Vaccine, Vol. 15, No. 6/7, 759-768, US Patent No. 6,127,116 (10/3/00), filed on 3/4/97 and hereafter referred to as Rice et al., and Lehner et al. (1999) J. Infect. Dis., Vol. 179 (Suppl 3), S489-S492, as applied to claims 1-2, 4-17, 20, and 29-30 above, and further in view of Barnett et al. (1997) Vaccine, Vol. 15(8), 869-873, is maintained over previously pending and new claims 21-27 and 31. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

Applicant's arguments are based on their previous argument that Hurpin in view of Hodge, Rice, and Lehner do not provide a reasonable expectation of success to arrive at the instant invention as claimed. These arguments have been fully considered and addressed in detail above and have not been found persuasive. Applicant's further argument that Barnett does not overcome the deficiencies of Hurpin, Hodge, Rice, and Lehner is not persuasive as the teachings of Hurpin, Hodge, Rice, and Lehner stand and Barnett was not cited to teach lymph node

administration, rather Barnett was cited to provide teachings and motivation to immunize using a prime/boost vaccination strategy which includes a priming step with a nucleic acid encoding an antigen and a boosting step with a protein form of the antigen. The applicant has not traversed these teachings, therefore, the rejection of record stands.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/
Primary Examiner, A.U. 1633